tests in animals used only for laboratory research purposes, or for in vitro or mechanical tests or similar tests that do not involve use of human subjects, shall be exempt from any of the otherwise applicable provisions of the act listed in §813.1(b) if:

(1) The labeling of the device complies with the requirements of §813.5 (a) and (b) and bears the following additional statement:

CAUTION—DEVICE FOR INVESTIGATIONAL USE ONLY IN LABORATORY ANIMALS OR OTHER TESTS THAT DO NOT INVOLVE HUMAN SUBJECTS

(2) The person who ships the device under this subpart uses due diligence to assure that the consignee is regularly engaged in conducting tests in animals used only for laboratory research, or similar for in vitro or other mechanical tests or tests that do not involve use of human subjects and that the shipment of the investigational device will actually be used only in such tests.

(3) The person who ships the device under this subpart maintains adequate records showing the name and address of the consignee to whom the device is shipped, date, quantity, and batch or code mark of each shipment for a period of 2 years after such shipment and, upon the request of a properly authorized employee of the Department at reasonable times, make such records available for inspection and copying or submits such records to the Food and Drug Administration.

(b) This subpart does not apply to any use of an investigational device that involves use of human subjects.

[42 FR 58889, Nov. 11, 1977, as amended at 53 FR 11253, Apr. 6, 1988]

§813.170 Termination of exemption.

(a) The commissioner shall terminate an exemption under this subpart if he makes either of the following findings:

(1) The person shipping an investigational device under this subpart has failed to comply with any of the conditions for the exemption under this subpart.

(2) Any of the grounds for withdrawal of an investigational device exemption under §813.35 apply.

(b) The Commissioner shall notify the sponsor of the termination of an exemption under this subpart with a full statement of the reasons for such termination and shall afford an opportunity for a regulatory hearing under Part 16 of this chapter. The person whose exemption is terminated shall recall or otherwise assure the destruction of any unused devices.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart A—General

Sec.

Subpart B—Premarket Approval Application (PMA)

Subpart C—FDA Action on a PMA

Subpart D—Administrative Review [Reserved]

Subpart E—Postapproval Requirements

AUTHORITY: Secs. 501, 502, 503, 510, 513–520, 701, 702, 703, 704, 705, 721, 708, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381).

SOURCE: 51 FR 26364, July 22, 1986, unless otherwise noted.